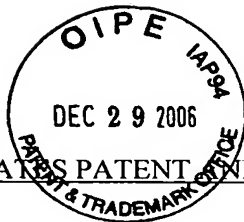


DOCKET NO.: 239770US0DIV



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: David LEWIS et al

SERIAL NO: 10/612,067

GROUP ART UNIT: 1616

FILED: July 3, 2003

EXAMINER: HAGHIGHATIAN, M.

FOR: PHARMACEUTICAL AEROSOL COMPOSITION

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicants wish to disclose the following information.

**REFERENCES**

- ☒ The Applicants wish to make of record the references listed on the attached Form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☒ A check or credit card payment form is attached in the amount required under 37 C.F.R. §1.17(p).

**RELATED CASES**

- ☐ Attached is a list of Applicants' pending application(s), published application(s) or issued patent(s) which may be related to the present application. In accordance with the waiver of 37 C.F.R. §1.98 dated September 21, 2004, copies of the cited pending applications are not provided. Cited published and/or issued patents, if any, are listed on the attached Form PTO-1449.
- ☐ A check or credit card payment form is attached in the amount required under 37 C.F.R. §1.17(p).

**CERTIFICATION**

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this statement.

**DEPOSIT ACCOUNT**

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to Deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

for -  (46,671)  
Stephen G. Baxter

Registration No. 32,884

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Customer Number

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Tel. (703) 413-3000  
Fax. (703) 413-2220  
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Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO. 239770US0DIV		SERIAL NO. 10/612,067	
<div style="border: 2px solid black; border-radius: 50%; padding: 10px; display: inline-block;"> O I P E DEC 29 2006 PATENT &amp; TRADEMARK OFFICE </div>				APPLICANT David LEWIS et al			
				FILING DATE July 3, 2003		GROUP 1616	
<b>U.S. PATENT DOCUMENTS</b>							
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE	
	AA	6,290,930	09/18/01	Frank E. BLONDINO et al			
	AB	5,653,961	08/05/97	Rebecca A. McNALLY et al			
	AC	6,451,285	09/17/02	Frank E. BLONDINO et al			
	AD	2003/0077230 A1	04/24/03	Frank E. BLONDINO et al			
	AE	6,645,466	11/11/03	Manfred KELLER et al			
	AF	6,149,892	11/21/00	Ignatius Loy BRITTO			
	AG	5,695,743	12/09/97	Tarlochan S. PUREWAL et al			
	AH	5,683,677	11/04/97	Tarlochan S. PUREWAL et al			
	AI	6,026,808	02/22/00	Thomas Alex ARMER et al			
	AJ	6,045,778	04/04/00	Paul Donald JAGER et al			
	AK	6,006,745	12/28/99	Paul E. MARECKI et al			
	AL	5,954,047	09/21/99	Thomas Alex ARMER et al			
	AM	5,435,297	07/25/95	Christoph KLEIN			
	AN	3,361,306	01/02/68	W. M. GRIM			
<b>FOREIGN PATENT DOCUMENTS</b>							
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	AO	WO 98/56349	12/17/98	WIPO			
	AP	WO 98/34595	08/13/98	WIPO			
	AO	WO 92/11236	07/09/92	WIPO			
	AR	WO 96/32150	10/17/96	WIPO			
	AS	WO 96/32151	10/17/96	WIPO			
	AT	WO 96/32345	10/17/96	WIPO			
	AU	WO 95/17195	06/29/95	WIPO			
	AV	0 504 112 A2	09/16/92	EPO (English Abstract provided)			XXX
<b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)</b>							
	AW	R.O. Williams III et al, "A study of an epoxy aerosol can lining exposed to hydrofluoroalkane propellants", <u>EUROPEAN JOURNAL OF PHARMACEUTICS AND BIOPHARMACEUTICS</u> , Vol. 44, pp. 195-203, (1997).					
	AX	ABPI COMPENDIUM OF DATA SHEETS AND SUMMARIES OF PRODUCT CHARACTERISTICS, Datapharm Publications Limited, London, pp. 81-82, (1996-97).					
	AY	Paul A. Sanders, Ph.D., "Homogeneous Systems and Their Properties", <u>HANDBOOK OF AEROSOL TECHNOLOGY</u> , Second Edition, Van Nostrand Reinhold Company, NY, pg. 30, 1979.					
	AZ	G. Brambilla et al, "Modulation of Aerosol Clouds Produced by HFA Solution Inhalers", <u>PORTABLE INHALERS</u> , pp. 155-159, (November 26 & 27, 1998).				<input type="checkbox"/> Additional References sheet(s) attached	
Examiner					Date Considered		
*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

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<b>U.S. PATENT DOCUMENTS</b>							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	3,622,053	11/23/71	John V. RYDEN			
	AB	2003/0157028 A1	08/21/03	David LEWIS et al			
	AC	4,835,145	05/30/89	Peter MacDONALD			
	AD	5,676,930	10/14/97	Paul D. JAGER			
	AE	6,413,496	07/02/02	Michael GOODMAN et al			
	AF	5,642,728	07/01/97	Jan ANDERSSON et al			
	AG	5,415,853	05/16/95	Helmut HETTCHE et al			
	AH	5,605,674	02/25/97	Tarlochan S. PUREWAL et al			
	AI	6,004,537	12/21/99	Frank E. BLONDINO et al			
	AJ	6,241,969	06/05/01	Zahir SAIDI et al			
	AK	2004/0047809 A1	03/11/04	David LEWIS et al			
	AL	5,192,528	03/09/93	R. RADHAKRISHNAN et al			
	AM	4,185,100	01/22/80	David T. ROVEE et al			
	AN	6,253,762	07/03/01	Ignatius Loy BRITTO			
<b>FOREIGN PATENT DOCUMENTS</b>							
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES                  NO		
	AO	WO 93/05765	04/01/93	WIPO			
	AP	WO 93/18746	09/30/93	WIPO			
	AQ	WO 94/21229	09/29/94	WIPO			
	AR	WO 93/11743	06/24/93	WIPO			
	AS	WO 98/01147	01/15/98	WIPO			
	AT	WO 98/13031	04/02/98	WIPO			
	AU	WO 00/35458	06/22/00	WIPO			
	AV	WO 00/78286	12/28/00	WIPO			
<b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)</b>							
	AW	B. Meakin, "Fine Particle Dose Control of Solution Based pMDIs", <u>DRUG DELIVERY TO THE LUNGS IX</u> , The Aerosol Society, pp. 1-20, (December 14 & 15, 1998).					
	AX	S.S. DAVIS, "Physico-Chemical Studies on Aerosol Solutions For Drug Delivery I. Water-Propylene Glycol Systems", <u>International Journal of Pharmaceutics</u> , 1, 1978, pp. 71-83.					
	AY	L. Harrison et al, "Twenty-eight-day Double-blind Safety Study of an HFA-134a Inhalation Aerosol System in Healthy Subjects", <u>J. Pharm. Pharmacol.</u> , 1996, Vol. 48, pp. 596-600.					
	AZ	P. Hoet et al, "Epidemic of liver disease caused by hydrochlorofluorocarbons used as ozone-sparing substitutes of chlorofluorocarbons", <u>The Lancet</u> , 1997, Vol. 350, pp. 556-559.				<input type="checkbox"/> Additional References sheet(s) attached	
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<b>U.S. PATENT DOCUMENTS</b>							
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	AA	2003/0066525	04/10/03	David LEWIS et al			
	AB	6,716,414	04/06/04	David LEWIS et al			
	AC	2004/0062720	04/01/04	David LEWIS et al			
	AD	4,499,108	02/12/85	Joel A. SEQUEIRA et al			
	AE	5,955,058	09/21/99	Paul Donald JAGER et al			
	AF	6,150,418	11/21/00	Dieter HOCHRAINER et al			
	AG	6,315,985	11/13/01	Zheng Z. WU et al			
	AH	6,143,277	11/07/00	Ian C. ASHURST et al			
	AI	2003-0089369	05/15/03	David LEWIS et al			
	AJ	6,045,784	04/04/00	Nicholas A. RUEBUSCH et al			
	AK	2005/0142071	06/30/05	David LEWIS et al			
	AL	2006/0083693	04/20/06	David LEWIS et al			
	AM	2006/0120966	06/08/06	Tanya K. CHURCH et al			
	AN	2005/0129621	06/16/05	Rebecca J. DAVIES et al			
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	AO	WO 99/65460	12/23/99	WIPO			
	AP	0 642 992 A2	03/15/95	EPO (English Abstract provided)			XXX
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	AS	0 911 048	04/28/99	EPO			
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	AU	WO 92/20391	11/26/92	WIPO			
	AV	WO 98/03533	01/29/98	WIPO			
<b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)</b>							
	AW	J. Daly, Jr., "Properties and toxicology of CFC alternatives", <u>Aerosol Age</u> , February 1990, pp. 26-27, 40, 56 and 57.					
	AX	D. Strobach, "Alternatives to CFCs" Part II, <u>Aerosol Age</u> , July 1988, pp. 32-33, 42 and 43					
	AY	Tsi-Zong Tzou et al, "Drug Form Selection in Albuterol-Containing Metered-Dose Inhaler Formulations and Its Impact on Chemical and Physical Stability", <u>Journal of Pharmaceutical Sciences</u> , 1997, Vol. 86, No. 12, pp. 1352-1357.					
	AZ	M.J. Kontny et al, "Issues Surrounding MDI Formulation Development with Non-CFC Propellants", <u>Journal of Aerosol Medicine</u> , 1991, Vol. 4, No. 3, pp. 181-187.				<input type="checkbox"/> Additional References sheet(s) attached	
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	AA	2005/0152846	07/14/05	Rebecca J. DAVIES et al			
	AB	4,584,320	04/22/86	David RUBIN et al			
	AC	5,776,433	07/07/98	Tsi-Zong TZOU et al			
	AD	4,579,854	04/01/86	Takeo IWAKUMA et al			
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	AU	WO 97/47286	12/18/97	WIPO			
	AV	2 326 334	12/23/98	GB			
<b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)</b>							
	AW	I. P. Tansey, "Changing to CFC-Free Inhalers: The Technical and Clinical Challenges", <u>The Pharmaceutical Journal</u> , 1997, Vol. 259, pp. 896-898.					
	AX	D. Tiwari et al, "Compatibility Evaluation of Metered-Dose Inhaler Valve Elastomers with Tetrafluoroethane (P134a), a Non-CFC Propellant, <u>Drug Development and Industrial Pharmacy</u> , 1998, Vol. 24, No. 4, pp. 345-352.					
	AY	<u>Handbook of Pharmaceutical Excipients</u> , 3rd Ed., Kibbe Editor, pp. 7-9, 220-222, 234-235 and 560-561.					
	AZ	L. I. Harrison et al, "Pharmacokinetics and Dose Proportionality of Beclomethasone From Three Strengths of A CFC-Free Beclomethasone Dipropionate Metered-Dose Inhaler", <u>Biopharmaceutics &amp; Drug Disposition</u> , 1997, Vol. 18, No. 7, pp. 635-643.				<input type="checkbox"/> Additional References sheet(s) attached	
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<b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)</b>							
	AW	Chet Leach, "Enhanced Drug Delivery Through Reformulating MDIs with HFA Propellants-Drug Deposition and Its Effect on Preclinical and Clinical Programs", <u>Respiratory Drug Delivery V</u> , 1996, pp. 133-144.					
	AX	G. Brambilla et al, "Modulation of Aerosol Clouds Produced By HFA Solution Inhalers", <u>Drug Delivery to The Lungs</u> , December 14-15, 1998, The Aerosol Society.					
	AY						
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